Contd

Atty Dkt No. 6200-0013
Serial No. 09/716,029

C9 33 96. (New) The pharmaceutical composition of claim 71, wherein said vitamin E substance is alpha-tocopherol or an individual enantiomer thereof.

REMARKS

The claims have been amended as discussed with Examiner Kwon. Those claims reciting a vitamin E substance as solubilizer have been canceled as a result of restriction, as also discussed. New claims 95-98 have been added, and are supported on pages 16-17, bridging paragraph.

Accordingly, as claims 1, 3, 4, 37, 38, 40-46, 50, 52, 53, 66, 72-91 have been canceled and new claims 95-98 have been added, with claims 10, 12, 51, 54, 59, 61-63, 67-71, and 92-94 having been amended, claims 51, 54-65, 67-71, and 92-98 are now pending. All pending claims are set forth in Appendix B.

Please note that applicants have canceled claims 1, 3, 4, 37, 38, 40-46, 50, 52, 53, 66, 72-91 and amended the remaining claims for consistency solely to remove non-elected subject matter. Cancellation of the aforementioned claims (and amendment of the remaining claims as a result) has been done without prejudice, without intent to abandon any previously claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants will pursue the subject matter of the now-canceled claims in a divisional application hereof, as discussed with Examiner Kwon.

As the application should now be in condition for allowance, a prompt mailing of the Notice of Allowance would be very much appreciated.

Respectfully submitted,

Date: 8/8/02

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APPENDIX A

REDACTED CLAIMS INDICATING AMENDMENTS MADE

Please cancel claims 1, 3, 4, 37, 38, 40-46, 50, 52, 53, 66, 72-91 without prejudice to further prosecution in a divisional or continuation application.

Amend claims 10, 12, 51, 54, 59, 61-63, 67-71, and 92-94 as follows:

10. (Twice Amended) The pharmaceutical composition of claim 54, wherein said solubilizer ~~is~~ comprises a mixture of a nitrogen-containing solvent and at least one of a trialkyl citrate and a lactone.

12. (Amended) The pharmaceutical composition of claim 10, wherein said ~~solubilizer~~ nitrogen-containing solvent is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

51. (Twice Amended) A method for treating a patient suffering from a ~~fenofibrate-responsive condition, disease or~~ lipid disorder, comprising administering to the patient a therapeutically effective amount of ~~any one of claims 1, 54 or 66~~ the composition of claim 54.

54. (Amended) A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of ~~a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof~~: a trialkyl citrate; a lactone; a combination of a trialkyl citrate and a lactone; a combination of a vitamin E substance and at least one of a trialkyl citrate, a lactone, and a nitrogen-containing solvent; and a combination of a nitrogen-containing solvent and at least one of a trialkyl citrate and a lactone.

59. (Amended) The pharmaceutical composition of claim 54, in a ~~semi-liquid~~ semi-solid form.

61. (Amended) The pharmaceutical dosage form of claim 60, ~~wherein the therapeutically effective amount of fenofibrate is~~ comprising a unit dosage form.

62. (Amended) The pharmaceutical dosage form of claim ~~60, wherein the unit dosage is from~~ 61, comprising about 40 mg to about 250 mg fenofibrate.

63. (Amended) The pharmaceutical dosage form of claim 62, ~~wherein the unit dosage is from~~comprising about 67 mg to about 200 mg fenofibrate.

67. (Amended) The pharmaceutical composition of claim ~~66~~ 54, wherein the fenofibrate has not been micronized.

68. (Amended) The pharmaceutical composition of claim ~~66~~ 54, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

69. (Amended) The pharmaceutical composition of claim ~~66~~ 54, wherein the solubilizer ~~is~~ comprises a combination of a vitamin E substance and at least one of a trialkyl citrate, a lactone, and a nitrogen-containing solvent.

70. (Amended) The pharmaceutical composition of claim 69, wherein the vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols, individual enantiomers thereof, and mixtures ~~thereof~~ of any of the foregoing. (Amended like claim 3)

71. (Amended) The pharmaceutical composition of claim 70, wherein the vitamin E substance is selected from the group consisting of alpha-tocopherol, alpha-tocopheryl acetate, alpha-tocopheryl acid succinate, alpha-~~tocopherol~~ tocopheryl polyethylene glycol 1000 succinate, individual enantiomers thereof, and mixtures ~~thereof~~ of any of the foregoing.

92. (Amended) The method of claim ~~91~~ 51, wherein the lipid disorder is an above-normal level of cholesterol.

93. (Amended) The method of claim ~~91~~ 51, wherein the lipid disorder is an above-normal triglyceride level.

94. (Amended) The method of claim ~~91~~ 51, wherein the lipid disorder is a below-normal level of high density lipoproteins.

Add the following new claims 95-98:

95. (New) The pharmaceutical composition of claim 71, wherein said vitamin E substance is alpha-tocopheryl polyethylene glycol 1000 succinate or an individual enantiomer thereof.

96. (New) The pharmaceutical composition of claim 71, wherein said vitamin E substance comprises a mixture of alpha-tocopheryl polyethylene glycol 1000 succinate and alpha-tocopherol.

97. (New) The pharmaceutical composition of claim 71, selected from the group consisting of d-alpha-tocopherol, d,l-alpha-tocopherol, d-alpha-tocopheryl acetate, and d,l-alpha-tocopheryl acetate.

98. (New) The pharmaceutical composition of claim 71, wherein said vitamin E substance is alpha-tocopherol or an individual enantiomer thereof.

APPENDIX B

PENDING CLAIMS UPON ENTRY OF THIS AMENDMENT

5. The pharmaceutical composition of claim 54, wherein said solubilizer is a trialkyl citrate.

6. The pharmaceutical composition of claim 5, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

7. The pharmaceutical composition of claim 6, wherein said trialkyl citrate is triethyl citrate.

8. The pharmaceutical composition of claim 54, wherein said solubilizer is a lactone.

9. The pharmaceutical composition of claim 8, wherein said lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and γ-butyrolactone and isomers thereof and mixtures thereof.

10. The pharmaceutical composition of claim 54, wherein said solubilizer comprises a mixture of a nitrogen-containing solvent and at least one of a trialkyl citrate and a lactone.

11. The pharmaceutical composition of claim 10, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

12. The pharmaceutical composition of claim 10, wherein said nitrogen-containing solvent is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

51. A method for treating a patient suffering from a lipid disorder, comprising administering to the patient a therapeutically effective amount of the composition of claim 54.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of: a trialkyl citrate; a lactone; a combination of a trialkyl citrate and a lactone; a combination of a vitamin E substance and at least one of a trialkyl citrate, a lactone, and a nitrogen-containing solvent; and a combination of a nitrogen-containing solvent and at least one of a trialkyl citrate and a lactone.

55. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in said composition.

56. The pharmaceutical composition of claim 55, wherein the fenofibrate is at least 75% solubilized in said composition.

57. The pharmaceutical composition of claim 56, wherein the fenofibrate is completely solubilized in the composition.

58. The pharmaceutical composition of claim 54, in a liquid form.

59. The pharmaceutical composition of claim 54, in a semi-solid form.

60. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

61. The pharmaceutical dosage form of claim 60, comprising a unit dosage form.

62. The pharmaceutical dosage form of claim 61, comprising about 40 mg to about 250 mg fenofibrate.

63. The pharmaceutical dosage form of claim 62, comprising about 67 mg to about 200 mg fenofibrate.

64. The pharmaceutical dosage form of claim 60, in capsule form.

65. The pharmaceutical dosage form of claim 60, in the form of a drink.

67. The pharmaceutical composition of claim 54, wherein the fenofibrate has not been micronized.

68. The pharmaceutical composition of claim 54, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

69. The pharmaceutical composition of claim 54, wherein the solubilizer comprises a combination of a vitamin E substance and at least one of a trialkyl citrate, a lactone, and a nitrogen-containing solvent.

70. The pharmaceutical composition of claim 69, wherein the vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols, individual enantiomers thereof, and mixtures of any of the foregoing.

71. The pharmaceutical composition of claim 70, wherein the vitamin E substance is selected from the group consisting of alpha-tocopherol, alpha-tocopheryl acetate, alpha-tocopheryl acid succinate, alpha-tocopheryl polyethylene glycol 1000 succinate, individual enantiomers thereof, and mixtures of any of the foregoing.

92. The method of claim 51, wherein the lipid disorder is an above-normal level of cholesterol.

93. The method of claim 51, wherein the lipid disorder is an above-normal triglyceride level.

94. The method of claim 51, wherein the lipid disorder is a below-normal level of high density lipoproteins.

95. The pharmaceutical composition of claim 71, wherein said vitamin E substance is alpha-tocopheryl polyethylene glycol 1000 succinate or an individual enantiomer thereof.

96. The pharmaceutical composition of claim 71, wherein said vitamin E substance comprises a mixture of alpha-tocopheryl polyethylene glycol 1000 succinate and alpha-tocopherol.

97. The pharmaceutical composition of claim 71, selected from the group consisting of d-alpha-tocopherol, d,l-alpha-tocopherol, d-alpha-tocopheryl acetate, and d,l-alpha-tocopheryl acetate.

98. The pharmaceutical composition of claim 71, wherein said vitamin E substance is alpha-tocopherol or an individual enantiomer thereof.